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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,240	06/30/2000	Matthew Joseph Doyle	8147	8182

27752 7590 08/28/2006

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/607,240	DOYLE ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,8 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment received 6/22/06 has been entered and claims 5, 6, 8, 10-21 are currently pending in this application.

In view of the amendments to the claims and applicants arguments, the rejections of record of claims 5-18 under 35 USC 101 and112, first paragraph, are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 8, 10-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition to the claims of "an oral bacterial-mediated systemic disease" is new matter. "Mediated" is the key word. If the disease is mediated by oral bacteria, one would the expect removing the oral bacteria would remove the disease. Therefor, would one of skill in this art expect treating oral bacteria to then treat systemic disease such as subacute bacterial endocarditis? Further, there are many disorders, such as a skin infection caused by candida where candida can also be an oral pathogen but the oral pathogen does not mediate the skin pathogen.

Claims 10-12, 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition to the claims of the limitation "in the absence of an H2 antagonist" is new matter. The specification as originally filed teaches on page 15 line 5 and page 31 first paragraph, various H2 antagonists that may be included in the composition. A negative limitation such as excluding a component requires definitive written description which is not found in the specification.

During prosecution of this application, claims 10-12 were amended to require that the composition not include H2 antagonists. In making this amendment, applicant did not point out where the original disclosure of this application describes this concept. Rather, it appears to have been inserted in an attempt to distinguish the invention from the Singer reference which includes H2 antagonists. We have reviewed the original disclosure of this application and do not find that it reasonably conveys the concept now claimed, i.e., that the present process is performed without the use of H2 antagonists. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); In re Winkhaus, 527 F.2d 637, 188 USPQ 129 (CCPA 1975).

Newly added claims 19-21 include the limitation "with the proviso that the composition may not include an H2-antagonist" where the same issue applies.

Applicant's arguments filed 6/22/06 have been fully considered but they are not persuasive.

Applicants argue that the claims can be interpreted to mean the amount of antimicrobial agent is measured in the absence of H2 antagonist but that the H2 antagonist may be present or not.

It is the examiner's position that the specification provides no written description for the claimed concept of excluding H2 antagonists. And as written the claims are ambiguous and can be interpreted as the composition contains an antimicrobial agent and does not contain an H2 antagonist.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13-18 are directed to known health markers as indicators of health as regarding bacterial mediated systemic disease. The specification provides no nexus between any such claimed marker and prevention or treatment of bacterial periodontal infection in the oral cavity. The examiner is unaware of any of the claimed markers alone being a reliable indicator of the presence or absence of periodontal disease and are so generally claimed as to be meaningless, for example, "disregulation of glucose metabolism."

No arguments are presented regarding the above rejection.

Claims 5, 6, 8, 19-21 are rejected under 35 USC 102(b) as being anticipated by Singer as was decided by the Board of Appeals in the decision rendered 3/26/04.

Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive.

Applicants argue that Singer requires an H2 antagonist and optionally an antimicrobial agent. The present claims require an antimicrobial agent and optionally can include an H2 antagonist. The teachings of Singer do not inherently result in promotion of whole body health. The claims have been amended to require the antimicrobial agent to control bacterial infection where Singe does not teach treating subject having or at risk of developing an oral bacteria-mediated systemic disease.

It is the examiner's position that the presently claimed method is clearly taught by Singer and therefor anticipates the present claims. A reading of Singer would lead one to immediately envision a composition containing both an H2 antagonist as well as an antimicrobial agent.

Regarding the issue already decided by the Board of Appeals regarding the inherency of promoting whole body health, one practicing all the presently claimed method steps would inherently also promote whole body health. Now, considering the function of the presently claimed invention as promoting whole body health in more detail, promoting does not require accomplishing to a great degree where no degree is

claimed, whole in context is undefined but may be considered to imply health beyond oral health alone. As such, the phrase is meaningless in context. For example, does taking a breath of air promote whole body health? Does drinking a sip of water promote whole body health? Does brushing one's teeth promote whole body health?

The nexus between oral health in general and brushing or otherwise cleaning teeth has been unassailable for centuries. So this discussion leaves us to decide whether there is any nexus to any degree between oral health in general and whole body health prior to 6/30/2000. It is the considered position of this examiner that due to the considerable percent of people whose death was caused by dental disease in pre-modern times which continues to this day in less developed populations, the nexus between serious illness, disability and death and dental disease would highly likely be well known. Further, it was well known at the time this invention was made that the health of carnivorous animals in the wild and in captivity is highly dependent upon their oral health. This examiner was witness to the deaths of many maned wolves in captivity due to periodontal disease that was resistant to treatment in the early 1980's. It would be likely that humans in contact with domesticated and wild animals would be well aware of the connection between oral infection, loss of teeth, loss of oral function and the attendant risk to health of the animals beyond these oral manifestations.

The teachings of Singer would inherently control bacterial infection and inhibit oral bacteria because Singer teaches applying the same composition to the same location. In the absence of any testing, the reduction in visible inflammation would be a standard indicator of reduction of infection where inflammation and infection have a

common nexus. One would expect infection to produce inflammation in the oral cavity. Regarding Singer specifically, the title of Singer is "Use of H-2 Antagonists for Treatment of Gingivitis" and the abstract include prevention or treatment of gingivitis or periodontitis. Treating those who have and may be at risk for developing periodontal disease with antibacterial compounds as claimed is old in this art. See mouthwash ads from the past few decades.

The dose ranges presently claimed and taught by Singer overlap. No advantages are disclosed for the presently claimed dose ranges.

Regarding the claimed population and the population of Singer, the subjects are humans with gingivitis or periodontitis which would therefor have some risk of systemic disease.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-12, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer.

The claims differ from Singer in that they exclude H2 antagonists in the composition, optionally or not.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to make oral care products containing other standard components as described by Singer with or without H2 antagonists because Singer describes specific functions of H2 antagonists for treating specific oral conditions and should one desire oral care products for other functions, one would not include H2 antagonists. Oral care products not containing H2 antagonists were known at the time this invention was made. No particular function to H2 antagonists is presently claimed. Further, as a negative limitation to not include H2 antagonists, no advantage is seen. An undisclosed advantage is given little or no patentable weight.

Applicant's arguments filed 6/22/06 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to encompass compositions that do include an H2 antagonist and the amount of the composition are effective to promote whole body health. The compositions of Singer include H2 antagonists.

It is the examiner's position that Singer does not require including H2 antagonists in the compositions shown. Promoting whole body health is properly interpreted in a broad fashion and is encompassed by the teachings of Singer who teaches treating periodontal disease. The present claims read on administering to the oral cavity compositions containing antimicrobial agents in most any known form. No nexus between any method of treating and effectively treating periodontal disease, nor any nexus between treating periodontal disease and "whole body health" is claimed. An no novelty is seen in such a nexus.

Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer.

The claims differ from Singer in that they specify particular markers of body health.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ any known marker of body health as an indicator of body health because all the claimed markers are employed in this art in some fashion as markers of some dysfunction or disorder. None alone however are reliable markers of bacterial periodontal infection.

Applicant's arguments filed 6/22/06 have been fully considered but they are not persuasive.

Applicants argue that the relation between bacterial infections of the oral cavity and systemic disease is novel.

It is the examiner's position that employing markers of disease is old and as claimed, treating oral infections inherently also treats systemic disease.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9, 13, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 8(b) "such as" does not state whether the components are or are not included. In claim 19 line7, "ICPC" is queried. In claim 21(a) what the amount is effective for has not been set forth.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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